IN THE UNITED STATES
DISTRICT COURT FOR THE
DISTRICT OF NEVADA

THOMAS C. BRADLEY
Sinai, Schroeder, Mooney, Boetsch & Bradley
448 Hill Street
Reno, Nevada 89501
702/323-5178

FILED March 20, 1997
BY: LANCE S. WILSON
DENTY CLERK

WM. BRADFORD REYNOLDS
Collier, Shannon, Rill & Scott, PLLC
3050 K Street, N.W.
Washington, D.C. 20007
202/342-8634

UNITED STATES OF AMERICA,	
Plaintiff,	
v.	CIV-N-93-194 ECR
CENTURY CLINIC, INC. a corporation,	PETITIONERS CENTURY CLINIC AND DR. KATRINA TANG'S OPENING BRIEF ON APPEAL FROM FDA'S FINDING ON CONTEMPT
and	
YIWEN TANG, M.D., an individual,	
and	
KATRINA TANG, H.M.D. an individual,	

I. The Standard Of Review In This Court

By its terms, the Consent Decree provides for the instant appeal of the FDA decision to this Court. See Admin. R., Vol. VII, Exh. J, para. 10, p. 8. It further specifies that "the arbitrary and capricious review standard of 5 U.S.C. § 706(2)(A)" shall be controlling. Id. at para. 11, p. 9. Under that standard, Petitioners must show that the agency decision lacks evidentiary support in the administrative record, or must be overturned because it rests on a clear error of law or fact. See e.g., Nevada Land Action Ass'n v. U.S. Forest Service, 8 F.3d 713, 716-17 (9th Cir. 1993), citing Citizens to Preserve Overton Park, Inc. v. Volpe, 401 U.S. 402, 416 (1971). While the arbitrary and capricious standard is indeed high, it is not intended to operate as a "rubber-stamp" for judicial affirmance. See, e.g., Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto Ins. Co., 463 U.S. 29, 43 (1983); Neighborhood TV Co. v. FCC, 742 F.2d 629, 639 (D.C. Cir. 1984). Rather, courts are required to examine the record before the agency in its entirety and determine whether it contains support for the decision below or is lacking in support. See, e.g., Motor Vehicle Mfrs. Ass'n. v. State Farm Mut. Auto Ins. Co., supra, 463 U.S. at 43. Most notably, in this connection, mere unsubstantiated allegations of misconduct, without more, will not be sufficient to sustain the agency action under review. See Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto Ins. Co., supra, 463 U.S. at 43.

II. The FDA Decision Rests On A Clear Error of Law Requiring Reversal

In this instance, the decision on review is the FDA's determination that Century Clinic and Dr. Tang acted in violation of the Consent Decree. Hearing Officer Frappaolo

took the position that the matter was nothing more than an administrative procedure for the assessment of penalty payments, not a contempt proceeding to ascertain whether Petitioners were not complying with a court order. See Hearing Officer Opinion, at p. 29, n.32, Admin. R., Vol. IX, Exh. MM. The Consent Decree itself disputes the Hearing Officer's characterization. It specifically identifies the administrative hearing involved here as one to determine whether "defendants have violated the decree." See Consent Decree, para. 10, p. 8, Admin. R., Vol VII, Exh. J. Moreover, the understanding that this language had reference to a contempt proceeding was not only Petitioners, but was also the understanding of the FDA.[50/] Indeed, no one disputes that the Consent Decree is a court order.[51/] Nor could they. See, e.g., Rufo v. Inmates of Suffolk County Jail, 502 U.S. 367, 378 (1992); United States v. Swift & Co., 286 U.S. 106, 114-15 (1932). As such, there is little room to argue that a charge of non-compliance with its terms does not sound in contempt. See, e.g., Interdynamics, Inc. v. Wolf, 698 F.2d 157, 159, 160 (3d Cir. 1982). The United States Supreme Court has said as much in Local No. 93, International Association of Firefighters v. Cleveland 478 U.S. 501, 518 (1986), observing that "non-compliance with a consent decree is enforceable by citation for contempt of court." It was, therefore, clear error for the Hearing Officer to

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50/ See FDA Notice of Non-Compliance Letter of February 25, 1994, Admin. R., Vol. VIII, Exh. GG; FDA Memorandum entitled "Contempt of Injunction," dated April 11, 1994, Admin. R., Vol. VIII, Exh. II; FDA "Memorandum in Support of Finding of Contempt . . .," dated September 1, 1994, Admin. R., Vol. IX, Exh. KK.

51/ See FDA "Memorandum In Support of Finding of Contempt . . . ," dated September 1, 1994, at p. 37, Admin. R., Vol. IX, Exh. KK.

portray this as an "assessment" matter for ascertaining civil money penalties.[52/]

Equally errant was his follow-on conclusion that the "preponderance of evidence" standard controlled the administrative review proceeding below. It is well settled that the applicable standard of review in a contempt proceeding is the "clear and convincing evidence" standard. See, e.g., Bella v. Idaho State Bd. of Corrections, 869 F.2d 461, 466 (9th Cir. 1989); see also, Falstaff Brewing Corp. v. Miller Brewing Co., supra, 702 F.2d at 777-78, n.1.[53/] This is much higher than a "preponderance of the evidence." See Vertex Distributing, Inc. v. Falcon Foam Plastics, Inc., 689 F.2d 885, 889 (9th Cir. 1982); In Re: Battaglia, 653 F.2d 419, 422 (9th Cir. 1981). It is, moreover, quite different from the "highly probable" standard adopted alternatively by the Hearing Officer. See Hearing Officer Opinion, at p. 29, Admin. R., Vol IX, Exh. MM. Thus, for one charging non-compliance of a consent

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52/ It is undeniably the case that the review undertaken by the Hearing Officer was concerned with allegations by the agency of unauthorized conduct under the Consent Decree, and Petitioners' denial of those accusations. That is at the very heart of a contempt proceeding. Plainly not at issue here was any "assessment of damages" controversy, or any sort of penalty "assessment" proceeding. Indeed, on that particular point, the Hearing Officer merely mechanically applied the Consent Decree penalty language. See Hearing Officer Opinion, at pp. 31-32, Admin. R., Vol. IX, Exh. MM.

53/ That standard is not avoidable because the charge of non-compliance is in this instance heard by agreement by the FDA. As the U.S. Supreme Court made clear in a directly analogous situation in Woodby v. INS, 385 U.S. 276, 285 (1966), where courts apply the "clear and convincing" standard in similar situations, and there exists no conflicting body of administrative law, the hearing administrative officer must follow suit.

decree to prevail, he must demonstrate, by clear and convincing evidence, not that a specific and definite order of the court was "probably" violated, but that it was in fact violated (Falstaff Brewing Corp. v. Miller Brewing Co., supra, 702 F.2d at 777-78, n.1), and that the violation occurred in deliberate defiance and willful disobedience of the court. Id. at 781, n.6, citing, Maggio v. Zeitz, 333 U.S. 56, 76 (1948). It is, in this connection, not regarded as contumacious conduct if the violation was technical or inadvertent and occurred notwithstanding that the accused party took "all reasonable steps within his power to insure compliance" with the court order. See Stone v. City and County of San Francisco, 968 F.2d 850, 856-57 (9th Cir. 1992), cert. denied, 506 U.S. 1081 (1993); Sekaquaptewa v. MacDonald, 544 F.2d 396, 404 (9th Cir. 1976), cert. denied, 430 U.S. 931 (1977); see also General Signal Corp. v. Donallco, Inc., 787 F.2d 1376, 1379 (9th Cir. 1986); Vertex Distributing, Inc. v. Falcon Foam Plastics, Inc., supra, 689 F.2d at 891-92.

Had this standard been properly applied below -- as the law requires -- Petitioners could never have been found in contempt. To the extent that they may have departed in some respects from the Consent Decree's requirements by allegedly deviating from the approved Investigational Plan (see Hearing Officer Opinion, at pp. 24-25, 28-29, Admin. R., Vol IX, Exh. MM) -- a proposition we dispute -- any such departure was in direct response to the instructions of Biosource -- as requirements imposed by the Sponsor in connection with the IRB-approved LISTEN System training program.[54/]

54/ James Clark testified that the IRB was fully informed at the time it approved the LISTEN System clinical investigation that the selected trainees were to practice on as many patients as possible as part of their pre-Level II certification training, without maintaining the conductance point

CONCLUSION

For all of the foregoing reasons, the decision of the FDA Hearing Officer finding Petitioners in contempt of the March 23, 1993 Consent Decree entered by this Court and imposing a penalty assessment of $400,000.00 must be reversed as arbitrary and capricious agency action.

Dated: March 20, 1997

Respectfully submitted,

/S/ Wm. Bradford Reynolds
Wm. Bradford Reynolds
COLLIER, SHANNON, RILL & SCOTT, PLLC
3050 K Street, N.W.
Washington, D.C. 20007
(202) 342-8634

Thomas C. Bradley
SINAI, SCHROEDER, MOONEY, BOETSCH & BRADLEY
448 Hill Street
Reno, Nevada 89501
(702) 323-5178

CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of the foregoing Petitioners' Opening Brief on Appeal From FDA Finding of Contempt, together with a copy of the bound administrative record filed with the Court (Volumes I-IX), were served by Hand Delivery this 20th day of March, 1997, upon counsel for the United States, Drake Cutini, Esq., Trial Attorney, Office of Consumer Litigation, U.S. Department of Justice, Washington, D.C. 20044.

/S/ Wm. Bradford Reynolds
Wm. Bradford Reynolds